K040241

JUN 2 5 2004

Genzyme Corporation
One Kendall Square
Cambridge, MA 02139

510(k) Summary of Safety and Effectiveness Information Upon Which An Equivalence Determination Could be Made

Trade or Proprietary Name:	N-geneous™ Wide Range CRP Reagent N-geneous™ Wide Range CRP Calibrator Set
Common or Usual Name:	C-Reactive Protein immunological test system Calibrator for C-Reactive Protein
Classification Name:	C-Reactive Protein immunological test system Calibrator, Primary
Manufacturer:	Genzyme Diagnostics One Kendall Square Cambridge, MA 02139-1562
Contact Person:	Fred D. Lasky, Ph.D., Director, Regulatory Affairs (617) 591-5512 Robert Yocher, Vice President, Regulatory Affairs (617) 768-6275

The use of the Genzyme N-geneous™ Wide Range CRP Reagent in the clinical laboratory setting is substantially equivalent to the Dade Behring N *High Sensitive* CRP method.

The Genzyme N-geneous™ Wide Range CRP Reagent is a two-reagent method for the quantitative measurement of CRP concentration from 0.04 to 320 mg/L in serum or plasma.

The test is an enhanced latex-agglutination turbidimetric immunoassay. Sample is added to a buffer solution and mixed with a suspension of mouse anti-human CRP monoclonal antibody, which is bound to latex. CRP binds to the latex-bound antibody, which agglutinates. The light scattering caused by the increase in particle size is used as a measure of CRP concentration. The amount of light scattering is proportional to the concentration of CRP in the sample.

N-geneous™ Wide Range CRP Calibrator Set is a stabilized human serum designed to be used to calibrate the N-geneous™ Wide Range CRP Reagent and is sold separately. The N-geneous™ Wide Range CRP Calibrator Set is traceable to CRM470, available from theInstitute for Reference Materials and Measurements (IRMM), and certified by the European Commission, Community Bureau of Reference (BCR).

Comparative performance studies were conducted using the N-geneous™ Wide Range CRP Reagent on the Hitachi 912 clinical analyzer and the Dade Behring N *High Sensitive* CRP method in which CRP was measured in 229 serum samples. The relationship between methods is:

N-geneous™ Wide Range CRP = 1.05 X (N *High Sensitive* CRP) – 0.31

Correlation coefficient (r) = 0.995

Precision studies were conducted using the N-geneous™ Wide Range CRP Reagent on the Hitachi 912 clinical analyzer. The studies were performed using sera that were stored frozen (-20°C) and thawed prior to use.

The mean, standard deviation (SD) and coefficient of variation (%CV) for within-run precision:

Control	1	2	3	4	5
Mean (mg/L)	0.30	1.00	2.97	51.3	202
SD (mg/L)	0.02	0.02	0.04	0.61	3.0
%CV	5.5	1.8	1.3	1.2	1.5

The mean, standard deviation (SD) and coefficient of variation (%CV) for total precision:

Control	1	2	3	4	5
Mean (mg/L)	0.30	1.00	2.97	51.3	202
SD (mg/L)	0.02	0.02	0.05	0.96	3.1
%CV	6.7	2.3	1.7	1.9	1.5

The N-geneous™ Wide Range CRP reagents yielded acceptable total precision.

These data demonstrate that the performance of the N-geneous™ Wide Range CRP Reagent in the clinical laboratory is substantially equivalent to the performance of a commercially available method.

In addition, N-geneous™ Wide Range CRP Reagent is substantially equivalent to a currently marketed method, in that they measure the same analyte and have the same intended use. Additionally, they both use the same sample matrices and utilize mouse monoclonal antibody to CRP. Furthermore, they measure concentration by the magnitude of particle agglutination and light scatter, are in ready-to-use liquid format and both are traceable to CRM470 reference material. The N-geneous™ Wide Range CRP Reagent differs from the Dade Behring N *High Sensitive* CRP method in that the N-geneous™ Wide Range CRP Reagent utilizes a turbidimetric technique, whereas the Dade Behring N *High Sensitive* CRP

is a nephelometric method. Also, the reportable range of the N-geneous™ Wide Range CRP Reagent is up to 320 mg/L before dilution is required, whereas the Dade Behring N *High Sensitive* CRP method requires additional on board sample dilution for concentrations above 11 mg/L. The N-geneous™ Wide Range CRP Reagent uses a set of five standards for calibration; the Dade Behring N *High Sensitive* CRP method has one calibrator.

N-geneous™ Wide Range CRP Calibrator Set is substantially equivalent to a currently marketed calibrator, the Dade Behring N Rheumatology Standard SL in that they are both used to establish calibration of CRP methods to be used for measurement of CRP in serum or plasma. Both are human serum-base materials that are traceable to CRM470 available from the Institute for Reference Materials and Measurements (IRMM), and certified by the European Commission, Community Bureau of Reference (BCR).

In lieu of a 510(k) statement under 513(i) of the Act, this information is provided as a 510(k) summary for disclosure to any other persons/companies without the specific written authorization from Genzyme Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Fred D. Lasky, Ph.D.
Director, Regulatory Affairs
Genzyme Corparation
500 Kendall Street
Cambridge, MA 02142

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Re: k040241
Trade/Device Name: N-geneous™ Wide Range CRP Reagent Kit
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCK, JIS
Dated: April 19, 2004
Received: April 21, 2004

Dear Dr. Lasky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040241

Device Name: N-geneous™ Wide Range CRP Reagent Kit

Indications For Use:

Reagents:

For the quantitative measurement of C-Reactive Protein (CRP) concentration in serum or plasma.

For In Vitro Diagnostic Use

Calibrator:

For the calibration of the N-geneousTM Wide Range CRP assay.

For In Vitro Diagnostic Use

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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